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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/434,345	11/05/99	BOULIKAS	T

HM22/0327

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EXAMINER	
KERR, I	
ART UNIT	**PAPER NUMBER**
1633	4

DATE MAILED: 03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/434,345	BOULIKAS, TENI	
	Examiner	Art Unit	
	Janet Kerr	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Election/Restriction

Claims 1-28 are pending.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 24a, 25, 26, and 27 been renumbered 25, 26, 27, and 28, respectively.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a method of producing cisplatin micelles, methods of using the cisplatin micelles, and the cisplatin micelles, and classified in class 424, subclasses 450 and 649, for example.

II. Claims 24-26, drawn to a method of inhibiting tumor growth in a subject by administering a transgene, classified in class 424, subclasses 450 and 649, and class 514, subclass 44, for example.

III. Claim 27, drawn to a composition comprising cisplatin micelles and oligonucleotides, ribozymes, triplex, or PNA, classified in class 424, subclasses 450 and 649, and class 514, subclass 44, for example.

IV. Claim 28, drawn to a composition comprising cisplatin micelles in combination with drugs, classified in class 424, subclasses 450 and 649, and class 514, subclasses 675 and 724, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I is distinct from Invention II as the method of Invention II requires different starting materials, and requires different technical considerations than that of Invention I. For example, the method of Invention I requires administration of cisplatin micelles to inhibit tumor growth whereas the method of Invention II requires the administration of cisplatin micelles comprising specific transgenes to inhibit tumor growth. The technical considerations required to reduce to practice the method of Invention II, which encompasses gene therapy, are not required to reduce to practice the method of Invention I. The differences between Invention I and Invention II are further underscored by their differences in classification.

Invention I is distinct from Inventions III-IV as the product produced by the method of Invention I are distinct from the products of Inventions III and IV. For example, the compositions of Inventions III and IV contain ingredients other than cisplatin, such as transgenes (Invention III) and drugs (Invention IV) which are not required for the composition of Invention I. The differences between Invention I and Inventions III-IV are further underscored by their differences in classification.

Invention II is distinct from Inventions III-IV because the cisplatin composition required to reduce to practice the method of Invention II is distinct from the cisplatin compositions of Inventions III and IV. Moreover, administration of the compositions of Inventions III-IV will have different physiological effects than the composition delivered in the method of Invention II. The differences between Invention II and Inventions III-IV are further underscored by their differences in classification.

Invention III is distinct from Invention IV as the cisplatin micelle composition of Invention III has different ingredients than that of Invention IV. For example, the composition of Invention III comprises nucleic acid molecules, i.e., ingredients which are not required to formulate the composition of Invention IV, which comprises drugs. Similar, the drugs of Invention IV are not

required in the formulation of the composition of Invention III. The differences between Invention III and Invention IV are further underscored by their differences in classification.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to the following patentably distinct species of the claimed invention:

1. Phosphatidyl glycerol lipid derivatives (in claim 3):

a) dipalmitoyl phosphatidyl glycerol (DPPG),

b) dimyristoyl phosphatidyl glycerol (DMPG),

c) dicaproyl phosphatidyl glycerol (DCPG),

d) distearoyl phosphatidyl glycerol (DSPG) and

e) dioleyl phosphatidyl glycerol (DOPG).

The phosphatidyl glycerol lipid derivatives are distinct, each from the other, as they are structurally and chemically distinct, and have different physicochemical properties.

2. Fusogenic peptides (in claim 5):

a) a free fusogenic peptide,

b) a fusogenic peptide-lipid conjugate, and

c) a fusogenic peptide-PEG-HSPC conjugate.

The fusogenic peptides are distinct, each from the other, as they are structurally and chemically distinct, and have different physicochemical properties.

3. Vesicle-forming lipids (in claim 11):

a) premade neutral liposomes comprising cholesterol, HSPC and (PEG)-HSPC,

b) lipids in solution,

c) lipids in powder, and

d) PEG-DSPE.

The vesicle-forming lipids are distinct, each from the other, as they are structurally distinct, and have different physicochemical properties.

4. Lipids for admixing with cisplatin micelles (in claim 13):

a) PEG-DSPE,

b) PEG-DSPC, and

c) hyaluronic acid-DSPE.

The lipids are distinct, each from the other, as they are structurally distinct, and have different physicochemical properties.

5. Genes recited in claim 24:

a) p53,

b) pax5, and

c) HSV-tk.

The genes are distinct, each from the other, as they are structurally distinct, and have different physiological effects.

6. Any one of the genes recited in claim 26:

a) IL-2,

b) IL-4,

c) IL-7,

d) IL-12,

e) GM-CSF,

f) IFN-gamma,

g) TNF-alpha,

h) RB,

I) BRCA1,

j) E1A, and

k) cytosine deaminase,

or combinations of the above genes with

l) 5-fluorocytosine,

m) bcl-2,

n) MDR-1,

o) p21,

p) p16,

q) bax,

r) bcl-xs,

s) E2F,

t) IGF-1,

u) VEGF,

v) TGF-beta.

The genes are distinct, each from other, as the recited genes are different structurally and functionally, and have different physiological effects.

Should applicants elect a combination of genes, applicants should specify the particular genes in the combination, i.e., elects should indicate which gene(s) of a-k is combined with which gene(s) of l-v.

7. Species recited in claim 27:

a) oligonucleotides,

b) ribozymes,

c) triplex, and

d) PNA.

The species are distinct, each from the other, as they are structurally and functionally distinct, and have different physiological effects.

8. Drug species recited in claim 28:

a) doxorubicin,

b) fluorodeoxyuridine,

c) bleomycin,

d) adriamycin,

e) vinblastine,

f) prednisone,

g) vincristine, and

h) taxol.

The drugs are distinct, each from the other, as they are structurally and functionally distinct, and have different physiological effects.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 4, 7, 9, 10, 12, 14, 15, 18, and 23 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to Deborah Clark, Supervisory Primary Examiner of Art Unit 1633, at (703) 305-4051. Any administrative or procedural questions should be directed to Kimberly Davis, Patent Analyst, at (703) 305-3015. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633.

Janet M. Kerr, Ph.D.
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Group 1600

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